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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/560,272	08/16/2006	Dominique M. Freeman	38187-2806.US	3313
77845	7590	10/01/2008	EXAMINER	
Goodwin Procter LLP Attn: Patent Administrator 135 Commonwealth Drive Menlo Park, CA 94025-1105			WINAKUR, ERIC FRANK	
			ART UNIT	PAPER NUMBER
			3768	
			MAIL DATE	DELIVERY MODE
			10/01/2008	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/560,272	<b>Applicant(s)</b> FREEMAN ET AL.	
	<b>Examiner</b> Eric F. Winakur	<b>Art Unit</b> 3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1)  Responsive to communication(s) filed on \_\_\_\_\_.
- 2a)  This action is **FINAL**.                      2b)  This action is non-final.
- 3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4)  Claim(s) 1-23 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5)  Claim(s) \_\_\_\_\_ is/are allowed.
- 6)  Claim(s) 1-9,11-15,17-19,21 and 22 is/are rejected.
- 7)  Claim(s) 10,16,20 and 23 is/are objected to.
- 8)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9)  The specification is objected to by the Examiner.
- 10)  The drawing(s) filed on 08 December 2005 is/are: a)  accepted or b)  objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11)  The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All    b)  Some \*    c)  None of:
1.  Certified copies of the priority documents have been received.
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>See Continuation Sheet</u> . | 6) <input type="checkbox"/> Other: _____  |

Continuation of Attachment(s) 3. Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :12/8/05; 4/4/07 (2); 4/14/08; 6/11/08; 6/24/08; 8/26/08.

## **DETAILED ACTION**

### ***Claim Objections***

1. Claims 7, 20, and 23 are objected to because of the following informalities: With regard to claim 7, it appears that the term “a” should be inserted before “handheld”. With regard to claim 20, it appears that the term “an” should be inserted before “array” (line 1). With regard to claim 23, it appears that that term “opens” (line 12) should read “open” and that the term “causing” (line 13) should read “causes” so that these terms are more grammatically correct in the phrases in which they appear. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 11, 12, 14, 15, 17 - 19, 21, and 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. With regard to claim 11, it is unclear what provides an antecedent basis for the phrase “each segment”. With regard to claim 12, although drawn to a device, the claim does not positively recite any structural limitations and therefore is not properly further limiting. With regard to claim 14, it is unclear what structure the phrase “only used if required” is intended to define. With regard to claim 15, it is unclear what structure Applicant intends the claim to cover, as the only positively recited structure is to the location of the detecting member, yet other limitations related to size and typical uses of the arrangement are also set forth;

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further it is uncertain if the additional limitations are meant to set forth claimed structure or are intended to be more exemplary in nature. With regard to claim 17, the claim is improperly set forth as a sentence fragment; a period should be added at the end of the claim; further, it appears that the term "and" or "or" or "and/or" should be inserted before "fill". With regard to claim 18, the claim is improperly set forth as a sentence fragment; a period should be added at the end of the claim; further, it appears that the term "a" should be inserted before "cartridge" and "mechanism" (or perhaps before "piercing") and the term "that" should be inserted before "opens" to clarify the claimed arrangement. With regard to claim 19, the claim should end with a period; the structure that Applicant intends to set forth cannot be determined from the claim language. With regard to claim 21, the phrase "at conforming to" is unclear. With regard to claim 22, the claim is drawn to an apparatus, but only sets forth method steps; further, the phrases "said enzyme area" and "the sensing area" lack antecedent basis.

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1 - 9, 11 - 13, and 17 - 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Aceti et al. (USPN 6,923,764 - cited by Applicant). Aceti et al. teach a monitor having a housing containing a plurality of needles, each separately extendable from the housing and in communication with reaction chambers (column 2,

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lines 13 - 44). Optical measurements from the reaction chambers provide data on the measured analytes (Figures 5 - 8 and the descriptions thereof; "Optical Detection Elements" portion of specification in column 10 - 11). The choice of reagent determines the assay that will be performed. Although Aceti et al. disclose monitoring of glucose as their preferred embodiment, it would have been within the skill level of the art at the time of the invention to provide additional assay reagents having properties as described by Aceti et al. ("Assay Reagents" - column 9 - 10) to allow the device to perform measurements for multiple analytes of interest with a single measurement system.

***Allowable Subject Matter***

6. The following is a statement of reasons for the indication of allowable subject matter: Applicant cites numerous references related to analyte measurement. However, the prior art does not teach or suggest any of: performing many tests with one penetrating member/analyte detecting member combination, the various configurations as set forth in claims 14 - 16, or a separate storage area with a sensing area and another storage area with the enzyme therein arranged so that fluid flow to the enzyme area and then the sensing area, in combination with the other claimed elements.

7. Claims 10 and 16 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

8. Claims 20 and 23 would be allowable if rewritten to overcome the objections set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

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9. Claims 14, 15, 21 and 22 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric F. Winakur whose telephone number is 571/272-4736. The examiner can normally be reached on M-Th, 7:30-5; alternate Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571/272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric F Winakur/  
Primary Examiner, Art Unit 3768